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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/647,979	08/26/2003	Bruce Fletcher Johnson	133976	2828
6147	7590	10/25/2006	EXAMINER	
GENERAL ELECTRIC COMPANY GLOBAL RESEARCH PATENT DOCKET RM. BLDG. K1-4A59 NISKAYUNA, NY 12309			SCHLIENTZ, LEAH H	
			ART UNIT	PAPER NUMBER
			1618	

DATE MAILED: 10/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/647,979

Applicant(s)

JOHNSON ET AL.

Examiner

Leah Schlientz

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 16-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 12/1/03 and 3/4/2005.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election of the following species in the reply filed on 9/25/2006 is acknowledged: saccharides as the targeting moiety, the structures of group iv as the leaving group (i.e. benzenesulfonate derivatives), silica as the solid support, and  $^{18}\text{F}$  as the detectable species. Claims 16 – 20 are pending.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 18 – 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Luthra (US 2004/0236085 filed 6/18/02, which claims benefit of GB 0115927.6 filed 6/29/01).

Luthra discloses a method of producing an imaging agent, 2-fluoro- $^{18}\text{F}$ -2-deoxy-D-glucose, or  $^{18}\text{F}$ -FDG. In general, the invention provides a process for the production of an  $^{18}\text{F}$ -labelled tracer (i.e. imaging agent) by treatment of a precursor of the following formula: SOLID SUPPORT-LINKER-X-TRACER, with  $^{18}\text{F}$  to produce a labeled tracer (paragraphs 0004 – 0006). The SOLID SUPPORT-LINKER-X portion is equivalent to the instantly claimed leaving group. Specifically, the tracer is a saccharide, X is a sulfonate, and the linker may be any suitable organic group which serves to space the reactive site sufficiently to the solid support structures. The linker may comprise from zero to four aryl groups (suitably phenyl) and/or a  $\text{C}_{1-6}$  alkyl or  $\text{C}_{1-6}$  haloalkyl (suitably  $\text{C}_{1-6}$  fluoroalkyl). See paragraphs 0026 – 0034, figure 1b, paragraph 0019; and claim 3).

Claims 18 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Johnson (US 5,264,570).

Johnson discloses a method of producing an imaging agent, 2- $^{18}\text{F}$ -fluoro-2-deoxy-D-glucose. A targeting moiety, an acetyl protected  $\beta$ -D-mannopyranose (i.e. a saccharide) is bound to a leaving group, a trifluoromethanesulfonyl group. Upon contacting the 1,3,4,6-tetra-O-acetyl-2-O-trifluoromethanesulfonyl-2-deoxy- $\beta$ -D-mannopyranose compound with a solution of  $^{18}\text{F}$ , the leaving group is substituted with

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the detectable species (i.e.  $^{18}\text{F}$ ), and the imaging agent,  $^{18}\text{F}$ -FDG is recovered (column 2, lines 53+, and claims 1 – 3).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 16 – 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Luthra (US 2004/0236085).

Luthra discloses precursor compounds and methods for producing an imaging agent, 2-fluoro-<sup>18</sup>F-2-deoxy-D-glucose, or <sup>18</sup>F-FDG, as set forth above. Luthra fails to specifically disclose that the linker should be benzenesulfonate with C<sub>4</sub>-C<sub>10</sub> in the para position.

The SOLID SUPPORT-LINKER-X-TRACER compounds taught by Luthra, which include a saccharide target and a sulfonate as the method of joining the target to the linker, which may be a phenyl and may also comprise a C<sub>1-6</sub> alkyl (i.e. may be a benzenesulfonate with C<sub>1-6</sub> alkyl), are within the scope of the instant limitation that a leaving group is benzenesulfonate derivative where X = C<sub>4-10</sub> alkylene. As such, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to utilize a benzenesulfonate derivative of group iv where X = C<sub>4-10</sub> alkylene as a leaving group in the preparation of an imaging agent, especially when bound to a solid support, with a reasonable expectation of success because benzenesulfonate leaving groups that may comprise a C<sub>1-6</sub> group has been taught by Luthra.

### ***Conclusions***


No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leah Schlientz whose telephone number is 571-272-9928. The examiner can normally be reached on Monday - Friday 8 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

lhs

  
MICHAEL G. HARTLEY  
SUPERVISORY PATENT EXAMINER